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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,690	03/10/2004	Madhwa H.G. Raj	Raj 02M27.1	7199

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PATENT DEPARTMENT
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EXAMINER
DUFFY, BRADLEY

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,690	RAJ ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/20/2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2 and 6, drawn to a method for inhibiting prostate cancer with antagonists comprising antibodies to riboflavin carrier protein, classified in class 424, subclass 130.1.

II. Claims 1, 2 and 7, drawn to a method for inhibiting prostate cancer with antagonists comprising antibodies to folic acid binding protein, classified in class 424, subclass 138.1.

III. Claims 1, 2 and 8, drawn to a method for inhibiting prostate cancer with antagonists comprising antibodies to retinol binding protein, classified in class 424, subclass 141.1.

IV. Claims 1, 3-5 and 6, drawn to a method for inhibiting prostate cancer with antagonists comprising oligonucleotides to riboflavin carrier protein, classified in class 514, subclass 45.

V Claims 1, 3-5 and 7, drawn to a method for inhibiting prostate cancer with antagonists comprising oligonucleotides to folic acid binding protein, classified in class 514, subclass 49.

VI. Claims 1, 3-5 and 8, drawn to a method for inhibiting prostate cancer with antagonists comprising oligonucleotides to retinol binding protein, classified in class 514, subclass 44.

VII. Claims 9, 10, 13, 14, 22 and 23, drawn to a method for inhibiting prostate cancer comprising immunization against heterologous riboflavin carrier protein or peptide subunits thereof, classified in class 514, subclass 2.

VIII. Claims 9, 11, 13, 15, 22 and 23, drawn to a method for inhibiting prostate cancer comprising immunization against heterologous folic acid binding protein or peptide subunits thereof, classified in class 514, subclass 12.

IX. Claims 9, 12, 13, 16, 22 and 23, drawn to a method for inhibiting prostate cancer comprising immunization against heterologous retinol binding protein or peptide subunits thereof, classified in class 424, subclass 184.1.

X. Claim 17, 18 and 21 drawn to a method for inhibiting prostate cancer comprising targeting prostate cancer cells with a vitamin-immunogen conjugate, wherein the vitamin is riboflavin, classified in class 514, subclass 79.

XI. Claim 17, 19 and 21, drawn to a method for inhibiting prostate cancer comprising targeting prostate cancer cells with a vitamin-immunogen conjugate, wherein the vitamin is folate, classified in class 514, subclass 85.

XII. Claim 17, 20 and 21, drawn to a method for inhibiting prostate cancer comprising targeting prostate cancer cells with a vitamin-

immunogen conjugate, wherein the vitamin is retinol, classified in class 514, subclass 11.

2. The inventions are distinct, each from the other because of the following reasons:

The methods of Inventions of Groups I-XII differ in the method objectives, method steps and parameters and in the reagents used. The invention of Group I recites inhibiting prostate cancer with antagonists comprising antibodies to riboflavin carrier protein. The invention of Group II recites inhibiting prostate cancer with antagonists comprising antibodies to folic acid binding protein. The invention of Group III recites inhibiting prostate cancer with antagonists comprising antibodies to retinol binding protein. The invention of Group IV recites inhibiting prostate cancer with antagonists comprising oligonucleotides to riboflavin carrier protein. The invention of Group V recites inhibiting prostate cancer with antagonists comprising oligonucleotides to folic acid binding protein. The invention of Group VI recites inhibiting prostate cancer with antagonists comprising oligonucleotides to retinol binding protein. The invention of Group VII recites inhibiting prostate cancer by immunizing subjects against riboflavin carrier protein or its peptide subunits. The invention of Group VIII recites inhibiting prostate cancer by immunizing subjects against folic acid binding protein or its peptide subunits. The invention of Group IX recites inhibiting prostate cancer by immunizing subjects against retinol binding protein or its peptide subunits. The invention of Group X recites inhibiting prostate cancer by challenging subjects

with an immunogen and then treating with an immunogen-vitamin conjugate, wherein the vitamin is riboflavin. The invention of Group XI recites inhibiting prostate cancer by challenging subjects with an immunogen and then treating with an immunogen-vitamin conjugate, wherein the vitamin is folate. The invention of Group XII recites inhibiting prostate cancer by challenging subjects with an immunogen and then treating with an immunogen-vitamin conjugate, wherein the vitamin is retinol.

The inventions of Groups I-XII are directed to methods that recite structurally and functionally distinct elements and are not required one for the other. The inventions of Groups I, II and III are all distinct from each other as the antibodies recognize different antigens and therefore differ structurally and functionally. For example, the antibody of Group I binds riboflavin carrier protein, which is not required by any of the other groups. The inventions of Groups IV, V and VI are all distinct from each other as the oligonucleotides have different sequences specific to the polynucleic acid they are inhibiting and therefore differ structurally and functionally. For example, the oligonucleotide of Group V inhibits the polynucleic acid for folic acid binding protein, which is not required by any of the other groups. Groups VII, VIII and IX are all distinct from each other as they are directed to methods that use different polypeptides with different structures and function. For example, the polypeptide of Group VIII binds folic acid with high affinity, while the others cannot. The inventions of Group X, XI, and XII are all distinct from each other as the immunogen-vitamin conjugates have an immunogen paired with different vitamins that vary structurally and functionally.

For example, the immunogen-folate conjugate of Group XI binds with high affinity to mutually exclusive polypeptides when compared to the other 2 groups. The inventions of Groups I-III use antibody antagonists consisting of amino acids while Groups IV-VI use oligonucleotide antagonists consisting of nucleotides that are structurally distinct. Furthermore, the inventions of Group I-III antagonize polypeptides after their synthesis, while the inventions of Group IV-VI antagonize polypeptides by preventing their synthesis and are therefore functionally distinct. The inventions of Groups I-III administer antibodies to target polypeptides while Groups VII-IX administer polypeptides to create an immunogenic response and therefore are structurally and functionally distinct. The inventions of Groups I-III use antibody antagonists consisting of amino acids while Groups X-XII use immunogen-vitamin conjugates that are structurally and functionally distinct. For example, the inventions of Group I-III target polypeptides, while the inventions of Group X-XII target the membranes of prostate cancer cells and therefore are structurally and functionally distinct. The inventions of Groups IV-VI use oligonucleotide antagonists consisting of nucleotides to alter polypeptide synthesis while Groups VII-IX administer polypeptides to create an immunogenic response and therefore are structurally and functionally distinct. The inventions of Groups IV-VI use oligonucleotide antagonists consisting of nucleotides to alter polypeptide synthesis while the inventions of Group X-XII target the membranes of prostate cancer cells and therefore are structurally and functionally distinct. The inventions of Groups VII-IX administer polypeptides to create an immunogenic response to polypeptides while the inventions of Group X-XII target

the membranes of prostate cancer cells and therefore are structurally and functionally distinct.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935